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10/566,941	08/28/2006	Cheryl J. Kojima	11916.0058.PCUS02	9166

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EXAMINER	
POHNERT, STEVEN C	

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
07/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/566,941	KOJIMA ET AL.	
	Examiner	Art Unit	
	Steven C. Pohnert	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *6-11,16,17 and 23-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12-15 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I claims 1-5, 12-15 and 18-22 in the reply filed on 4/14/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 6-11, 16-17, 23-24 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/14/2008.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of genotyping one or more pigs for traits capable of modulating meat quality comprising: obtaining a biological sample from a pig, detecting at least one polymorphism in the porcine leptin receptor, establishing the genotype of the pig and selecting a pig with the genotype, does not reasonably provide enablement for a method of genotyping any animal by detecting a polymorphism in the porcine leptin receptor. The specification does not enable any person skilled in the art

to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors have been described by the court in re Wands, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in the Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and the breadth of the claims:

The claims are broadly drawn to genotyping "any" animal by obtaining a sample from "any" animal, detecting at least one polymorphism in the porcine leptin receptor, establishing a genotype for the animal.

Claim 2, draws the claims to establishing a trait based on the polymorphism selected from: average feed intake, average daily weight gain, muscle mass, back fat, water holding capacity, meat color, meat pH, intramuscular fat, meat tenderness, and/or cooking loss.

The amount of direction or guidance and the Presence and absence of working examples.

The specification teaches characterization of polymorphisms in swine (pigs) in example 1. The specification further teaches sequencing of clone porcine leptin receptors in example 2. The specification further teaches methods of detecting porcine leptin receptor in example 3. The specification in example 4 teaches association studies between polymorphisms in the porcine leptin receptor in pigs and weight, lean mass percentage, backfat thickness, Loin color, weight gain (see tables 5-7). The specification in example 5 teaches methods of determining linkage disequilibrium.

The specification does not teach methods of genotyping and trait selection in any species other than pig.

The state of prior art and the predictability or unpredictability of the art:

Brenner et al (Trends in Genetics (2001) volume 17, pages 414-418) teaches that, "Here, the 'homology-implies-equivalency' assumption is restricted to a subset of homologs that diverged in the most-recent common ancestor of the species sharing the homologs. This strategy is useful, of course. But it is likely to be far less general than is widely thought. Two species living in the same space, almost by axiom, cannot have identical strategies for survival. This, in turn, implies that two orthologous proteins might not contribute to fitness in exactly the same way in two species" (see page 414, 3rd column last full paragraph). Brenner specifically describes that although the leptin gene homologs have been found in mice and humans, their affect is different (see page 414, 3rd column last paragraph-3rd column page 415). Brenner specifically teaches that the

leptin gene in mice plays a major role in obesity, but no such effect has been demonstrated in humans due perhaps to the different evolutionary forces. Brenner thus teaches that the activity and function of genes in different species is unpredictable.

The level of skill in the art:

The level of skill in the art is deemed to be high

Quantity of experimentation necessary:

In order to practice the invention as claimed, one would first have to establish that a predicative relationship exists between mutations in the porcine leptin receptor in "any" animal and average feed intake, average daily weight gain, muscle mass, back fat, water holding capacity, meat color, meat pH, intramuscular fat, meat tenderness, and/or cooking loss. Experimentation would be replete with unpredictable trial and error analysis because the specification does not teach that polymorphisms in the porcine leptin receptor are associated with any trait in "any" other species. Brenner teaches that different genes have different physiological affects as they are the result of different evolutionary forces. Thus it would be unpredictable to use the association of a single mutation with meat quality in "any" animal without specific guidance in the art or specification.

Due to the scope of the claims, one of skill in the art would be required to further undertake extensive trial and error experimentation to determine if polymorphisms in the porcine leptin receptor are indicative of altered meat quality in any species other than porcine.

Therefore, in light of the breadth of the claims, the lack of guidance in the specification, the high level of unpredictability in the associated technology, the nature of the invention, the negative teachings in the art, and the quantity of unpredictable experimentation necessary to practice the claimed invention, it would require undue experimentation to practice the invention as claimed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5, 12-15, 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 are indefinite because it lacks a positive active step relating back to the preamble. The preamble recites a method of genotyping one or more animals, however the last positive active step is drawn to selecting the animal having the genotype to provide the selected trait. Therefore it is unclear as to whether the method is drawn to genotyping one or more animals or selecting the animal having the genotype to provide the selected trait.

Claims 14-15 are indefinite because it lacks a positive active step relating back to the preamble. The preamble recites a method of enhancing a trait, however the last positive active step is drawn to using selected pigs in a breeding plan. Therefore it is unclear as to whether the method is drawn to of enhancing a trait or using selected pigs in a breeding plan.

Claim 18 is indefinite because it lacks a positive active step relating back to the preamble. The preamble recites a method of enhancing meat production, however the last positive active step is drawn to selecting pigs and repeating. Therefore it is unclear as to whether the method is drawn to enhancing meat production or selecting pigs and repeating.

Claim 19 is indefinite because it lacks a positive active step relating back to the preamble. The preamble recites a method of fixing an allele in a pig population, however the last positive active step is drawn to selecting pigs and repeating. Therefore it is unclear as to whether the method is drawn to fixing an allele in a pig population or selecting pigs and repeating.

Claims 20-22 are indefinite because it lacks a positive active step relating back to the preamble. The preamble recites a method of altering the frequency of an allele in a pig population, however the last positive active step is drawn to selecting pigs and breeding pigs. Therefore it is unclear as to whether the method is drawn to altering the frequency of an allele in a pig population or selecting pigs and breeding pigs.

7. Claims 3, 5, 12, 14, 15, 18, 19, 20, recites the limitation "the prepro-pLEPR polymorphism". There is insufficient antecedent basis for this limitation in the claim. Further it is unclear what is encompassed by "prepro-LEPR polymorphism" as while the specification recites, "prepro-LEPR polymorphism" it does not describe what is encompassed. This rejection can be easily overcome by amending the claims to recite "LEPR polymorphism." Dependent claims 13, 21, and 22 are rejected as they depend from claims 12 and 20 which lack antecedent basis.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 2, 4 are rejected under 35 U.S.C. 102(a) and 120(e) as being anticipated by Rothschild et al (US Patent 6,458, 531 published Oct 1, 2002, filed Oct 9, 1996).

With regards to claim 1, Rothschild teaches a method of genotyping a pigs for a lower fat content based on the presence of polymorphisms in the leptin receptor (see abstract). Rothschild teaches obtaining samples from a pig, analyzing genomic DNA, determining alleles present and correlating the genotype to leanness (see column 3, lines 28-35).

With regards to claim 2, Rothschild teaches the polymorphisms are associated with leanness of meat. Leanness is a measure of intramuscular fat and thus anticipates claim 2.

With regards to claim 4, Rothschild teaches the use of RFLP (see column 5, lines 36-41).

10. Claims 1, 2, 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Ovilo et al (Genetic Selection Evolution (2002) volume 34, pages 465-479).

With regards to claim 1, Ovilo teaches a method of genotyping the porcine leptin receptor by obtaining a sample from an animal, detecting polymorphism is the LEPR gene and establishing the genotype of the animal (see page 469). Ovilo further teaches correlating the genotype with a phenotype (see Table IV).

With regards to claim 2, Ovilo teaches determination of intramuscular fat percentage (see page 467, last full paragraph).

With regards to claim 4, Ovilo teaches RFLP analysis (see page 469, 1st paragraph).

11. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardage et al (27th international conference on animal Genetics, Minnesota, Conference abstract book, International Society of Animal Genetics, University of Minnesota, 2000, p65).

With regards to claim 1, Hardage teaches two polymorphisms in the Leptin receptor were identified in 390 F2 pigs (see abstract). Hardage teaches the LEPR genotypes were significant associated with lean meat content (P=0.0001), back fat (p=0.0006) and meat to fat ratio (p=0.001). Hardage thus teaches a method of obtaining a biological sample detecting at least one polymorphism in the porcine leptin receptor, establishing a genotype for the animal and selecting animals.

With regards to claim 2, Hardage teaches back fat as a phenotype associated with porcine leptin receptor genotype.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 3-5, 12-15, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardage et al (27th international conference on animal Genetics, Minnesota, Conference abstract book, International Society of Animal Genetics, University of Minnesota, 2000, p65) in view of Xiaoxiang et al (Chinese Science Bulletin (2001) volume 46, pages 396-400) and Rujuan et al (Proceedings International Conference on Animal biotechnology (1997) pages 96-100).

It is noted that claims 12 is drawn to a method of screening pigs to identify the nature of an allelic variant of either threonine of methionine at amino acid position 69 of pLEPR, selecting pigs that have "any" desired allele and using the selected pigs for breeding. The claim does not require the detection of threonine of methionine at amino acid position 69 of pLEPR or use of an allelic variant at position 69 as the allele for selection.

It is noted that claims 14 is drawn to a method of enhancing trait selection comprising identify the nature of an allelic variant of either threonine of methionine at amino acid position 69 of pLEPR, selecting pigs that have "any" desired allele and using the selected pigs for breeding. The claim does not require the detection of threonine of methionine at amino acid position 69 of pLEPR or use of an allelic variant at position 69 as the allele for selection.

It is noted that claims 15 is drawn to a method of enhancing a desired allele in a pig herd comprising identify the nature of an allelic variant of either threonine of methionine at amino acid position 69 of pLEPR, selecting pigs that have "any" desired allele and using the selected pigs for breeding. The claim does not require the detection of threonine of methionine at amino acid position 69 of pLEPR or use of an allelic variant at position 69 as the allele for selection.

It is noted that claims 18 is drawn to a method of enhancing a desired allele in a pig herd comprising identify the nature of an allelic variant of either threonine of methionine at amino acid position 69 of pLEPR, selecting pigs that have "any" desired allele and using the selected pigs for breeding. The claim does not require the

detection of threonine of methionine at amino acid position 69 of pLEPR or use of an allelic variant at position 69 as the allele for selection.

It is noted that claims 19 is drawn to a method of enhancing a desired allele in a pig herd comprising identify the nature of an allelic variant of either threonine of methionine at amino acid position 69 of pLEPR, selecting pigs that have "any" desired allele and using the selected pigs for breeding. The claim does not require the detection of threonine of methionine at amino acid position 69 of pLEPR or use of an allelic variant at position 69 as the allele for selection.

It is noted that claims 20 is drawn to a method of altering allele frequency in a pig population comprising identify the nature of an allelic variant of either threonine of methionine at amino acid position 69 of pLEPR, selecting pigs that have "any" desired allele and using the selected pigs for breeding. The claim does not require the detection of threonine of methionine at amino acid position 69 of pLEPR or use of an allelic variant at position 69 as the allele for selection.

Hardage teaches two polymorphisms in the Leptin receptor were identified in 390 F2 pigs (see abstract). Hardage teaches the LEPR genotypes were significant associated with lean meat content (P=0.0001), back fat (p=0.0006) and meat to fat ratio (p=0.001). Hardage thus teaches a method of obtaining a biological sample detecting at least one polymorphism in the porcine leptin receptor, establishing a genotype for the animal and selecting animals. Hardage teaches back fat as a phenotype associated with porcine leptin receptor genotype.

Hardage does not teach detection of threonine/methionine at amino acid position 69 (claim 3). Hardage does not teach restriction fragment length polymorphism (claim 4). Hardage does not teach detection a T or a C at the second position of amino acid 69 of the pLEPR (claim 5, 13). Hardage does not teach selecting and breeding pigs having a desired allele (claims 12, 14, 15, 18, 19, 20-22). Hardage does not teach breeding to increase or decrease the frequency of an allele.

Xiaoxiang teaches the OBR (leptin receptor) gene is thought to play a major role in regulating body weight and body fat mass (see abstract). Xiaoxiang teaches that molecular understanding of leptin receptor is a prerequisite to the rational utilization of leptin-based marker selection in pig breeding (see page 396, 2nd column, last paragraph). Xiaoxiang teaches sequencing of the pig LEPR gene (see page 399, 2nd column, 1st full paragraph). Xiaoxiang teaches the pLEPR sequence with comprises the codon for amino acid 69 (see figure 5). Xiaoxiang teaches his study allows for further investigation into the function of pLEPR as a tool to improve porcine traits of lean percentage and fat content (see page 399, last paragraph).

Rujuan et al teaches that pLEPR may represent a quantitative loci which controls body fat content, food intake and satiety in pigs (page 96, last paragraph). Rujuan teaches the sequence of a pLEPR gene with a T at the second position of the codon for amino acid 69 and teaches a C has been found at the position in other LEPR genes (see figure 3).

Therefore it would have been prima facie obvious to one of skill in the art at the time the invention was made to combine the teaches of Hardage, Xiaoxiang and Rujuan

to provide a method to genotype the porcine leptin receptor and correlate the polymorphisms in the receptor with meat quality traits. The artisan would be motivated to combine the teachings of Hardage, Xiaoxiang and Rujuan because all three teach or suggest the use of polymorphisms in the pLEPR for correlation and analysis of porcine meat quality. The artisans would be motivated to specifically detect the presence of codon 69 and/or the presence of a threonine or methionine in the pLEPR because Xiaoxiang and Rujuan teach a sequence with a T at the second nucleotide of the codon for amino acid 69 and Rujuan teaches a C occurs at the position in other LEPR genes. The artisan would have a reasonable expectation of genotyping and breeding the pigs as both the porcine LEPR sequence was known and breeding of pigs to improve meat quality were known.

Summary

No claims are allowed over prior art cited.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Sarae Bausch/
Primary Examiner, Art Unit 1634